

NOV 29 2006

VIII. 510(k) Summary of Safety and Effectiveness**Arthrex Interference Screw**

Manufacturer / Sponsor Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(k) Contact: Ann Waterhouse, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1179
FAX: (239) 598-5508

Trade Name: Arthrex Interference Screw

Common Name: Fastener, Fixation, bone, degradable and nondegradable

Product Code / HWC, 21 CFR 888.3040
MAI, 21 CFR 888.3030
MBI, 21 CFR 888.3040

Classification Name: Fixation, Fastener, bone

Predicate Device: Arthrex Interference Screw, K052607

Device Description and Intended Use:

The Arthrex Interference Screws are intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone. Interference fixation with PEEK, Titanium, or Bioabsorbable Polymer Interference Screws is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically;

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

Substantial Equivalence:

The Arthrex Interference Screw is substantially equivalent to the predicate Arthrex Interference Screw in which the basic features and intended uses are the same. Any differences between the Arthrex Interference Screw and the predicate are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the PEEK, PLLA, and Titanium Interference Screw are substantially equivalent to the currently marketed predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex, Inc.
% Ann Waterhouse, RAC
Project Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K062466
Trade/Device Name: Interference Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Codes: MAI, MBI, HWC
Dated: November 6, 2006
Received: November 8, 2006

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a small "for" written below the main name.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use Form

510(k) Number (if known): K062466

Device Name: Arthrex Interference Screw

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OED)

Charles E. Thompson
Division Sign-Off
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**Division of General, Restorative,
and Neurological Devices**

510(k) Number K062466